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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,123	06/15/2001	Laurie E. Locascio	P07097US01/RFH	7930
881	7590	06/18/2004	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			GAKH, YELENA G	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,123

Applicant(s)

LOCASCIO ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 39-44 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/15/01, 10/08/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Election of claims 1-29 and 39-44 filed on 05/03/04 is acknowledged.

Claim Objections

2. Claim 1 is objected to because of the following informalities: it recites, “alternating layers of at least one net positively charged layer **or** net negatively charged layer”. There should be “and” instead of “or”, since if the layers are alternating, both types of the layers must be present. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7-13 and 18 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. Specific structural relation between negative and positive layers in the microchannel and the lid critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification including drawings specifically discloses several embodiments for various structural relations between positively and negatively charged portions of the microchannel in order for the microchannel device to be enabled. Such relations are missing from the indicated claims, and therefore the device recited is not enabling. For example, it is not clear, how the microchannel surface should be charged, if the lid is covered with the polyelectrolite layers both positively and negatively charged, as recited in claim 7, to make the device operable.

Claims 8 and 9 are not enabled, since they omit the structural element, which makes the device enabled, i.e. the oppositely charged part of the microchannel. The microchannel cannot

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be positively or negatively charged without e.g. lid having the opposite charge to neutralize the microchannel charge.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 8-18, 21 and 39-44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 are missing an essential structural part, i.e. the oppositely charged part of the microchannel.

Claim 10 is indefinite regarding portions of the microchannel, which are positively and negatively charged. The structure of the microchannel device with such general description is unclear and indefinite.

Claims 11-13 are unclear regarding the disposition of polyelectrolyte layers relative to the structures of the microchannel recited in the claims, which makes the claims unclear and indefinite.

Claims 14-17 are written in an unclear language. It is hard to understand from the claims, how charges are delocalized in the microchannel.

The expression "a second portion of said microchannel surface of at least one of said at least three arms has a charge opposite a charge on an outmost layer of said polyelectrolyte layers disposed on said first portion and said second portion of a remaining arm" of claim 14 is quite cumbersome and unclear. If the parent claim 11 recites two possible arrangements of subchannels, namely T-shaped and cross-shaped, claim 14 must recite charged arms, rather than "first portion", "second portion", etc. What are these portions of the microchannel, if not the arms? The embodiments disclosed in the specification and depicted on drawings must be clearly recited in the claims.

In claim 17 it is not clear, if the negatively and positively charged portions of the bottom surface of the microchannel are transverse or parallel to the channel length, which is essential for forming a flow of a sample.

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Claim 21 recites a geometry of the microchannel selected from “trapezoidal, semicircular, rectangular, and square”. Microchannel is a three-dimensional figure and therefore cannot be characterized with two-dimensional geometrical shapes. It appears that the claim recites the shape of a cross-section of the microchannel, in which case it should recite exactly that.

In claim 39 it is not clear, what are “a first microchannel wall portion” and “a second microchannel wall portion” – are these two portions of the same microchannel wall? The structure of the microchannel with the oppositely charged two portions of the same microchannel wall is not clear; the microchannel with such structure does not seem to be operable.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 1-2, 5, 8-9, 11-13, 21 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martynova et al. (Anal. Chem., 1997, IDS) in view of Katayama et al. (Anal. Chem., 1998).

Martynova teaches "fabrication of plastic microfluid channels by imprinting methods" with reference to the prior art, which discloses "photolithographic processing techniques ... to produce channels in the surface of a planar substrate that are then covered with a plate of similar material" (Title and page 4783, right column). Martynova uses PMMA- instead of glass or silica- or silicon-based substrates. Cross-shaped microchannel with four arms is presented on Figure 2. Although Martynova does not specifically disclose T-shaped pattern consisted of three arms, it would have been obvious for anyone of ordinary skill in the art to modify the shape of the channel depending on the application of the device.

Martynova does not specifically teach polyelectrolyte layers disposed along at least a portion of a microchannel surface, comprising layers with alternating charges.

Katayama discloses successive multiple ionic-polymer (SMIL) "capillary coating with successive multiple ionic polymer layers for capillary electrophoresis" (Title and left column on page 5272).

It would have been obvious for anyone of ordinary skill in the art to modify Martynova's plastic (PMMA) microfluidic channel with the lid made of the same material (PMMA), as taught by the prior art disclosed by Martynova, with SMIL layers disclosed by Katayama, in order to use them specifically for electrophoresis, especially because Katayama demonstrated their exceptional efficiency as a capillary electrophoretic device.

11. **Claims 3-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martynova in view of Katayama, as applied to claims 1-2, 5, 8-9, 11-13, 21 and 29 and further in view of Tronin et al. (Colloid and Polymer Science, 1994, Abstract).

Martynova in view of Katayama do not specifically disclose negative charged layers comprising poly(styrene sulfonate) (PSS) and positively charged layers comprising poly(allylamine hydrochloride) (PAH).

Tronin discloses self-assembled polyelectrolytes comprising PSS and PAH with very homogenous characteristics (as found from their refractive indices independent on the thickness).

It would have been obvious for anyone of ordinary skill in the art to use PSS and PAH as negative and positive polyelectrolytes in polyelectrolyte multilayers in Martynova-Katayama's multichannel device, because Tronin demonstrates that they are easily self-assembled polyelectrolytes with homogenous characteristics.

12. **Claims 10 and 39-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martynova in view of Katayama, as applied to claims 1-2, 5, 8-9, 11-13, 21 and 29 in view of Stroock.

Martynova in view of Katayama do not specifically disclose two portions of the microchannel surface oppositely charged.

Stroock discloses "patterning electro-osmotic flow with patterned surface charge", with the microchannel surface having two portions oppositely charged (Figure 1a).

It would have been obvious for anyone of ordinary skill in the art to modify Martynova-Katayama's microchannel device by having two portions of the microchannel surface oppositely charged, as taught by Stroock, because this provides specific electro-osmotic flow pattern desirable in a variety of applications (see Introduction).

13. **Claims 19 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martynova in view of Katayama, as applied to claims, and further in view of Caruso et al. (JACS, 1999).

Martynova in view of Katayama do not specifically teach proteins, antibodies or DNA disposed within selected layers.

Caruso teaches "protein multiplayer formation on colloids through a stepwise self-assembly technique", indicating that "the L-b-L [layer-by-layer] method has been widely employed for the formation of multiplayer films of a wide array of water-soluble proteins, alternatively assembled with oppositely charged polyelectrolytes" (page 6039, right column).

It would have been obvious for anyone of ordinary skill in the art to modify Martynova-Katayama's microchannel device by having proteins disposed with the selected layers of polyelectrolyte, as indicated by Caruso, because they are "widely used in the areas of diagnostics, isolation, and localization in biotechnology" (page 6039, right column).

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14. **Claims 43 and 44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martynova in view of Katayama and Stroock, as applied to claims 10 and 39-42, and further in view of Tronin et al.

Martynova in view of Katayama and Stroock do not specifically disclose negative charged layers comprising poly(styrene sulfonate) (PSS) and positively charged layers comprising poly(allylamine hydrochloride) (PAH).

Tronin discloses self-assembled polyelectrolytes comprising PSS and PAH with very homogenous characteristics (as found from their refractive indices independent on the thickness).

It would have been obvious for anyone of ordinary skill in the art to use PSS and PAH as negative and positive polyelectrolytes in polyelectrolyte multilayers in Martynova-Katayama-Stroock's multichannel device, because Tronin demonstrates that they are easily self-assembled polyelectrolytes with homogenous characteristics.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Nelson et al. (US 5,770,029)* discloses integrated electrophoretic microdevices comprising a microchannel and a lid; *Soale et al. (US 5,858,188)* discloses acrylic microchannels and their use in electrophoretic applications; *Barker et al. (Anal. Chem., 2000)* disclose the instant invention; *Ladam et al. (Biomolecules, 2000)* teach protein interactions with polyelectrolyte multilayers, including polystyrene sulfonate/polyallylamine multilayers; *Pfohl et al. (Langmuir, 2001)* teach "controlled modification on microstructure silicon surfaces".

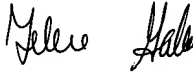
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
6/14/04

Handwritten signature of Yelena G. Gakh in black ink.